



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

**Note to Reader**  
**September 9, 1998**

**Background:** As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply, EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, if unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

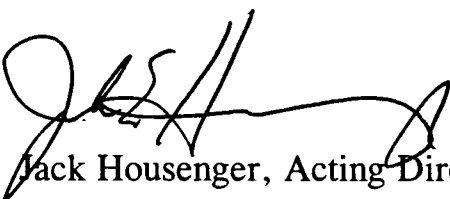
There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues

available in the information in this docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

**Note:** This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket ( RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.



Jack Housenger, Acting Director  
Special Review and Reregistration  
Division



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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Office of Prevention, Pesticides, and Toxic Substances

August 30, 1996

**MEMORANDUM:**

**SUBJECT:** EFED Risk Characterization and Recommendations for the  
Reregistration of Profenofos (List B; Case 2540; PC Code 111401)

**FROM:** David Farrar, RED team coordinator  
Science Analysis and Coordination Staff  
Environmental Fate and Effects Division

**THROUGH:** Kathy Monk, Acting Chief  
Science Analysis and Coordination Staff  
Environmental Fate and Effects Division

**TO:** Kathleen Depukat, Acting Chief  
Accelerated Reregistration Branch  
Special Review and Reregistration Division

Profenofos is an organophosphorus insecticide registered for use on cotton, and is applied by aerial or ground spray.

The EFED has reviewed available studies on environmental fate and ecological effects of profenofos. There are some significant gaps in the information available; however, the EFED is not requesting additional information as a precondition for reregistration. This communication presents findings on risk, recommendations for additional data, mitigation, monitoring, and labelling, and issues that need to be resolved. Text for Section III.C of the RED has been provided in a separate communication (memo 6/17/96 D. Farrar to K. Depukat). An additional copy of that document is attached.

Regarding environmental fate data, the EFED believes that the data available is relatively complete for profenofos parent but contains substantial gaps related to profenofos degradates. An adequate assessment of environmental fate properties will be possible with submission of a field dissipation study, if the study is designed to fill remaining data gaps, in particular if the

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study evaluates both parent profenofos and profenofos degradates. This additional information could substantially alter the fate assessment.

Based on the information available, the EFED *does not find concerns for quality of ground water*. Profenofos was not found to be persistent or highly mobile in soil under the conditions evaluated for the studies available. However additional information is recommended for fate characterization. Profenofos *does have potential to contaminate surface water*, particularly via spray drift and to some extent by runoff.

The EFED believes that the current use of profenofos results in *substantial risk to terrestrial and aquatic nontarget species*. To address risk to nontarget aquatic organisms, the EFED recommends a minimum buffer of 150 feet from edge of field to aquatic habitat. This will not significantly reduce concerns for effects on terrestrial species. Reductions in risk to nontarget terrestrial species may be achieved by rate reductions.

Additional effects information is recommended:

- Fish full life cycle study;
- Chronic estuarine/marine toxicity.

## Use Profile

Profenofos is a broad-spectrum acaricide and insecticide. The product Curacron 8E is registered for use on cotton, for control of mites and bollworm. Curacron 8E contains 8 pounds active ingredient per gallon. It is applied as an emulsifiable concentrate in aerial and ground spray at a maximum rate per application of 1 lb a.i./A and a maximum rate per year of 4.5 lb a.i./A. Information on the magnitude of use (acres treated and lb ai per year) is provided below in the Risk Characterization.

## Concerns

The following concerns are discussed in detail below in the Risk Characterization, and in the RED.

**Risk to Water Resources.** The information available to the Agency does not suggest concerns for quality of *ground water*, but additional data are recommended. Profenofos may contaminate *surface water* via spray drift and to a lesser degree by runoff. Concern levels are exceeded for some aquatic organisms (see below).

**Risk to Nontarget Terrestrial Organisms.** Chronic and acute levels of concern are exceeded for birds and small mammals.

**Risk to Nontarget Aquatic Organisms.** Levels of concern are exceeded as follows:

- Freshwater invertebrates, acute and chronic concerns;
- Estuarine/marine invertebrates, acute concerns;
- Estuarine/marine fish, acute concerns.

Toxicity data are not available for chronic effects on estuarine/marine fish or invertebrates.

## Data Gaps

**Environmental Fate.** Information is needed on environmental fate properties of profenofos degradates in soil. There is inadequate data on metabolism and dissipation of profenofos in acidic soils, despite the fact that cotton is grown in the southeast, where soils tend to be relatively acidic.

The most significant information gaps can be fulfilled by an appropriately designed field dissipation study. The study should be designed to represent conditions typical for application to cotton in humid areas of the southeast, a region where profenofos use is concentrated, and should be designed to provide information on fate properties of profenofos degradates.

**Ecological Effects.** There are no data available for *chronic toxicity to estuarine and marine organisms*. The EFED recommends estuarine/marine toxicity information particularly for insecticides used on cotton. A *fish full life cycle study* is also recommended to better characterize the risk to freshwater species. The fact that estimated environmental concentrations substantially exceed no-effect concentrations from a fish early life stage study suggest that the fish full life cycle study could substantially affect the assessment of chronic risk to fish.

## Risk Reduction Measures and Monitoring

Profenofos is applied by aerial or ground spray. The EFED recommends a minimum buffer of 150 feet from edge of field to aquatic habitat. This will often not result in reduction of effects on terrestrial species. Additional reduction in risk can be obtained by use rate reductions. Label language is recommended to address surface water contamination by drift, runoff, or accidental spillage. Specific language is suggested below.

## Label Precautions

Labels for manufacturing use products and end use products should include precautionary language related to hazard to nontarget species:

"This product is toxic to birds, fish, and aquatic invertebrates."

Manufacturing-Use product labels should include language regulating releases to the environment:

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."

For End-Use Product labels the EFED recommends language to control surface water contamination by runoff, drift, or accidental spillage.

- To prevent direct contamination of surface water:

"For terrestrial uses. Do not apply to water or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinseate."

- Additional label language will be required specifying buffer areas for control of spray drift.
- For contamination of surface water via spray drift: For aerial application, end-product labels should include standard language requiring best management practices for aerial spray drift management. It is EFED's understanding that SRRD now inserts this language for pesticides with spray application.
- For contamination of surface water via runoff:

"Under some conditions profenofos may contaminate surface water by runoff from treated land, for several days following application. These conditions include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and highly erodible soils cultivated using poor agricultural practices such as conventional tillage and down the slope plowing, and areas where an intense or sustained rainfall is forecasted to occur within 48 hours."

## **Risk Characterization.**

**Overview of chemical, magnitude of use.** Profenofos is a broad-spectrum organophosphate insecticide and acaricide, registered only for cotton. Some information on use is provided under "use profile" above. Of particular significance with regard to possible environmental impacts is the application procedure, which is by aerial or ground spray.

Information on total use and geographic and seasonal patterns of use can help to characterize the possible environmental impacts. The OPP has not held a "use meeting" with the registrant. The following information has been supplied by A. Grube of BEAD (8/5/95), synthesized from Doane, NCFAP, USDA-NASS, REFS, and TIS. Use appears concentrated in Louisiana, Texas, Mississippi, Alabama, and Georgia. Usage acres and pounds a.i. appear to have fluctuated during the period 1987 to 1991 and then to have increased more recently (see table).

### Magnitude of Annual Profenofos Use.

Period	acres treated (millions)	pounds active ingredient (millions)
1987-1991	0.2 to 0.8	0.2 to 1
1992	1.	1.5
1993	1.5	2.

The EFED has not obtained information on the seasonal timing of profenofos application. Such information would be used to characterize the risk to local nontarget populations or ecosystems.

**Fate in Soil, and Risk to Ground Water Quality.** Available environmental fate studies show that profenofos is *not persistent*, particularly in neutral and alkaline soils. Hydrolysis is the major route of dissipation while photolysis is not a major pathway. Hydrolysis is enhanced by metabolic processes. Additional biotic processes -- aerobic and anaerobic metabolism -- become important after the initial hydrolysis. Profenofos dissipates in neutral to alkaline soils, with a half-life of several days. *Little data exists for acid soils*, although it can be inferred that profenofos dissipates at a *slower rate in more acid soils*.

Because of the rapid hydrolysis of profenofos in both soil and water at least under alkaline to neutral pH (half life not over 3 days) environmental impacts could be due largely to profenofos degradates. Important gaps in our information relate to the environmental fate and ecological effects properties of the degradates. Available information on fate properties of profenofos degradates is discussed in the EFGWB review; in particular Appendices A and B of the EFGWB review provide graphical depiction of profenofos degradates and proposed degradation pathways. One of the major degradates, 4-bromo-2-chlorophenol (BCP), is persistent in the environment while the fate of another degrade, O-ethyl-S-propyl phosphorothioate, is not well known. We think it is likely that both degradates have fate and toxicity properties significantly different from those of parent profenofos. Additional metabolites apparently result from reactions involving BCP and O-ethyl-S-propyl phosphorothioate.

Profenofos is *not highly mobile* and, although the field dissipation studies did not allow for an assessment of the leaching potential, is *not expected to leach to ground water under normal use*. *The mobility and leaching potential of the degradates is unknown*.

Information is needed on the mobility of BCP and on the persistence, mobility, and dissipation pathways of O-ethyl-S-propyl phosphorothioate. EFED believes that adequate characterization of environmental fate properties of profenofos parent and degradates can be obtained by an appropriately designed terrestrial field dissipation study. Terrestrial field dissipation studies should be designed to provide an assessment of the leaching potential of profenofos and *both* of the degradates identified in soil and climatic conditions that favor water movement down through the soil.

The use information provided by BEAD indicates that use is concentrated in Texas and the southeast. In order to obtain information under an appropriate range of environmental conditions, we have indicated that a field dissipation study should be designed to represent conditions typical for application to cotton in humid regions of the southeast. In particular, relatively acidic soils are typical of the southeast.

**Risk to terrestrial nontarget species.** The following summarizes results from Section III.C.3 of the RED, which are based on standard criteria for categorizing toxicity and for determining concerns based on risk quotients (RQs). Exposures were estimated based on an assumed application rate of 1 lb a.i./A.

Regarding toxicity to *birds*, profenofos can be characterized as *moderately toxic to birds* on an *acute oral basis*, *moderately to highly toxic on a subacute dietary basis*. Risk quotients evaluated based on five types of food items were as high as 4 (for short range grasses). (The concern criterion is an RQ equal to 0.5 or larger.) Profenofos is highly toxic to birds on a *chronic* basis and significantly effects reproduction. Risk quotients were evaluated for the same five types of forage, resulting in values as high as 24. The concern criterion is an RQ equal to 1 or larger.

For *honeybees*, profenofos is highly *acutely* toxic. Risk quotients were not obtained.

For *small mammals*, toxicity findings from the HED RED chapter suggest that profenofos is moderately toxic on an acute basis, following the EFED system for categorizing toxicity. RQ values were calculated for three body weights and three types of food items (see table). The results suggest a concern for acute risk to small mammals.

#### **Risk Quotients for Small Mammals.**

Body Weight (g)	Type of Food Item		
	Short Grass	Forage and Small Insects	Large Insects
15	0.76 *	0.18	0.05
35	0.53 *	0.13	0.03
1000	0.12	0.03	0.01

\* Concern based on  $RQ > 0.5$ .

The exposure estimates used to calculate RQs for terrestrial nontarget species are based on information in Kenaga (1973) and Fletcher *et al.* (1994). These estimates are considered reasonable for exposure soon after application, and are therefore reasonable for assessing acute risk. Continued exposure to parent profenofos will be affected by degradation. Degradation is rapid under the conditions studied in soil and water, but degradation has not been studied for other media that could be significant for exposure to nontarget species, in particular on surfaces of plants.

**Risk of surface water contamination.** Profenofos *can contaminate surface water during application via spray drift*. A substantial proportion of applied profenofos should be available for runoff immediately following application, but after a few days the proportion available for runoff will be limited, because of rapid degradation in soil. Profenofos degradates will be available for runoff longer.

**Persistence** in surface water will depend on environmental conditions. Because of rapid hydrolysis and biodegradation, profenofos is not likely to persist in alkaline waters or in waters that have substantial microbial activity. It is likely to be somewhat more persistent in neutral to acidic waters with low microbial activities and long hydrologic residence times. Profenofos will probably not persist in normally anaerobic sediments.

Although no direct soil/water partitioning data are available for the major degradates, a greater partitioning of both BCP and cyclohexadienyl sulfate (CHDS) into water than profenofos in the aquatic anaerobic metabolism study suggests they may exhibit substantially lower soil/water partitioning than profenofos. (Under anaerobic conditions, CHDS is probably generated from phenol, which is in turn derived from BCP.) If so, runoff of those degradates may occur primarily by dissolution in runoff water instead of adsorbed to eroding soil, and most of their mass in receiving waters may be dissolved in the water column instead of adsorbed to suspended and bottom sediment.

**Risk to aquatic nontarget species.** The RQs reported here for aquatic species are based on Tier II exposure estimates (PRZM and EXAMS models).

Profenofos is highly toxic to fresh water fish and aquatic invertebrates, on both an acute and chronic basis. It is also very highly toxic to estuarine and marine organisms on an acute basis. There are no data available for chronic toxicity to estuarine and marine organisms. Risk quotients indicate concerns (see table).

Because profenofos hydrolyzes rapidly at least under the conditions measured (alkaline to neutral pH), chronic impacts could be due to relatively longer-lived degradates such as BCP, or could result from multiple applications. Also, it is not generally known whether or not the types of measurement endpoints observed in chronic toxicity studies actually require chronic exposure.

The EFED has little information on environmental fate and ecological effects of profenofos degradates in aquatic or terrestrial environments. However, predictions based on chemical structure (obtained from Office of Toxic Substances) suggest "moderate concern for acute toxicity" of BCP and "high concern for chronic toxicity." These results were obtained by Pauline Wagner, now detailing in EFED from OTS. OTS views such results as the best predictions based on results for structurally similar compounds. The general reliability of such results has not been addressed in EFED.

A fish full life cycle study is desirable to more fully characterize the chronic risk to fish, because the estimated exposure exceeds seven-fold the early life stage NOEC.

## Risk Quotients for Fish and Aquatic Invertebrates

Species		Acute RQ <sup>1</sup>	Chronic RQ <sup>2</sup>
<i>Daphnia</i>	(freshwater)	6.4	4.4
Pink shrimp	(estuarine/marine)	1.3	-
Pinfish	(estuarine/marine)	0.8	-

<sup>1</sup> The criterion for an *acute* concern is  $RQ \geq 0.5$ .

<sup>2</sup> The criterion for a *chronic* concern is  $RQ \geq 1$ .

**Issues of mutual interest to EFED and HED.** Members of the EFED team have met with the HED coordinator to discuss issues of mutual interest.

The BEAN sheet for EFED indicates that **dioxin** is a possible contaminant of starting material, but no specific tasks were identified for EFED related to that possibility. Based on the evaluation by HED, EFED assumes that dioxin is essentially absent from end-use products. Therefore, EFED has not considered the issue of possible dioxin contamination in Section III.C of the RED.

The EFED surface water section has indicated that surface water treatment facilities may not be completely effective in removing profenofos from drinking water. This possibility was raised with HED. EFED also raised the possibility of health effects associated with profenofos degradates.



## **EFED Reregistration Team for Profenofos**

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cc

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List B Files